

## STATUS OF RE-REGISTERED PATIENTS FOR TUBERCULOSIS TREATMENT UNDER DOTS PROGRAMME

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### Summary

**Objective:** To assess the proportion of patients re-registered after default, failure or successful treatment, completion and evaluate their treatment outcome.

**Setting:** Tuberculosis patients diagnosed were registered for treatment under DOTS in rural area, South India. Patients re-registered during 1999-2004 identified from the TB register were considered for analysis.

**Results:** Among 273 Category-I patients 'defaulted' 23% and among 112 'failure' cases 68% were re-registered. After 'successful treatment completion' of 1796 cases 6.5% were re-registered as relapse. Corresponding figures for Category II were 20% of 281 defaulters; 23% of 60 failures; 12.9% of 302 'successful treatment completion' patients. Among patients re-registered as 'default', subsequent default was also high (57% vs 37%). Failure in Category II treatment was similar among patients who were re-registered for Category II and initially registered in it for treatment. Median delay for re-registration was >200 days for 'defaulters' and 18 days for 'failures'.

**Conclusion:** Our findings emphasise the need for continuing motivation and prompt defaulter retrieval action to reduce default at all stages of treatment. 'Defaulters' need to be contacted so that they can be started on treatment without delay. Patients declared as 'successful treatment completion' should be encouraged to report if chest symptoms recur. [*Indian J Tuberc* 2007; 54:12-16]

**Key words:** Re-registration, DOTS, Tuberculosis, Default

## INTRODUCTION

The Revised National Tuberculosis Control Programme (RNTCP) based on the World Health Organization's Directly Observed Treatment-Short Course (DOTS) strategy was launched by Government of India in a phased manner since 1993. The progress of patients started on treatment is monitored and treatment outcome given as per international definitions<sup>1</sup>. Patients who are declared as 'failure' or relapsed after being declared as 'cure' or 'treatment completed' and 'default' after receiving one month or more of treatment will be re-registered for treatment under Category II. Not much information is available on the proportion of patients re-registered and their treatment outcomes according to type at re-registration. This paper presents data on the above issues.

## MATERIAL AND METHODS

The DOTS programme was implemented in 1999 in the study area of Tiruvallur district, Tamil Nadu covering a population of 580,000. Patients diagnosed with tuberculosis in this area were registered for treatment under DOTS. All patients registered from May 1999 to 2004 were considered for the analyses. **A patient was considered as re-registered for treatment if he/she was already registered previously for treatment in the same Tuberculosis Unit (TU).**

### Data collection

The details of the patients registered for treatment under DOTS were collected from the Tuberculosis (TB) register maintained in the TU. A patient started on treatment is assigned a unique TB

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number along with the year of registration. When a patient is re-registered, a new TB number will be allotted at the time of re-registration.

### Statistical analyses

The data from TB register after scrutiny were computerized, verified keying in twice, edited and corrected for discrepancy and missing information. The Chi-square test was used to test difference in proportions. The level of statistical significance was defined as  $P < 0.05$ .

### RESULTS

From May 1999 through December 2004, 2608 patients were started on Category I treatment, 803 on Category II, 1844 on Category III and 111 on non-DOTS (non-DOTS excluded for analysis).

Of 2287 new smear positive patients registered in Category I, 1796 (79%) had 'successful treatment completion', 273 (12%) 'Defaulted', 99 (4%) 'Expired', and 112 (5%) 'Failed' and 7 (<1%) were 'transferred out'. Corresponding figures for 699 smear positive Category II patients were 302 (43%), 281 (40%), 47 (7%), 60 (9%) and 9 (1%), and for 2165 new smear negative and extra pulmonary patients (including 321 smear negative and extra pulmonary TB patients treated with Category I) were 1814 (84%), 231 (11%), 89 (4%), 27 (1%) and 4 (<1%) respectively. A total of 444 (403 smear-positive and 41 smear-negative) patients were re-registered during 1999-2004, including 57 patients who were re-registered twice and eight 3-times and one 4-times in the same TU. Of the patients registered between 1999 and 2004, 273 patients were re-registered of whom 248 (91%) were re-registered within 2-years (Table 1).

**Table 1:** Year of initial registration and re-registration of patients treated under DOTS

Admission		Re-Registration					
Year	No.	2000	2001	2002	2003	2004	Total
1999	407	32	14	5	1	0	52
2000	970	10	55	31	11	3	110
2001	1046	-	25	55	26	5	111
2002	1097	-	-	18	62	19	99
2003	947	-	-	-	12	51	63
2004	899	-	-	-	-	9	9

**Table 2:** Proportion of patients re-registered according to Category of patients started on treatment and its outcome (May 1999 –Dec 2004).

Started treatment	Treatment outcome*				Treatment Success	
	Default		Failure			
	Total	Re-registered (%)	Total	Re-registered (%)	Total	Re-registered (%)
Category-I Smear Positive	273	64(23)	112	76(68)	1796	117(6.5)
Category-II Smear Positive	281	56(20)	60	14(23)	302	39(12.9)
New Smear Negative and Extra Pulmonary	231	16(7)	27	21(78)	1844	25(1.4)

\* 16 re-registered cases excluded (1 'transfer out', 8 non-DOTS and 7 Category II smear negative)

The proportion re-registered according to initial category and treatment outcome is given in Table 2. From Category I smear positive patients, 64 (23%) of 273 'defaulted', 76 (68%) of 112 'failures' and 117 (6.5%) of 1796 'treatment success' patients were re-registered for treatment. The corresponding figures for Category II patients were 20%, 23% and 12.9% and for new smear negative and extra pulmonary cases 7%, 78% and 1.3%, respectively. We have excluded 1 patient from the 'transfer out', 8 started on non-DOTS treatment and

7 Category II smear negative at the time of re-registration.

The median interval between declaring the treatment outcome and re-start of treatment was 228 days for 109 'default' and 18 days for 105 'failure' and 212 days for 163 'relapse' patients (Table 3).

Of the 57 patients who were re-registered for the second time, 23 were defaulters, 16 relapses, 10 failures, 4 were re-registered as 'new' cases and 4 as others.

**Table 3:** Median interval between declaration of treatment outcome and re-start of treatment

Outcome	Category I Smear positive.		Category II Smear positive		New Smear negative and Extra Pulmonary		Total (No. in first time re-registration)	
	No.	Median days	No.	Median days	No.	Median days	No.	Median days
Default	64	228	56	224	16	438	136 (104)	234 (230)
Failure	76	18	14	72	21	12	111 (104)	19 (18)
Relapse	117	219	39	198	25	192	181 (161)	210 (212)

**Table 4:** Treatment outcome according to type at the time of re-registration and initially registered as Category II Smear positive cases

Type	Treatment outcome					
	Total	Treatment Success (%)	Default (%)	Died (%)	Failure (%)	Others (%)
Default Re-Registered Initially Category II*	117 215	31(26) 98(46)	67(57) 79(37)	11(9) 17(8)	7(6) 16(7)	1(1) 5(2)
Failure Re-Registered Initially Category II*	104 34	37(36) 15(44)	44(42) 12(35)	6(6) 3(9)	17(16) 3(9)	- 1(3)
Relapse Re-Registered Initially Category II*	131 95	64(49) 55(58)	49(37) 29(31)	6(5) 4(4)	11(8) 6(6)	1(1) 1(1)
Total Re-Registered Initially Category II*	352 344	132(38) 168(49)	160(45) 120(35)	23(7) 24(7)	35(10) 25(7)	2(1) 7(2)

\* includes cases registered at the commencement of DOTS, previously treated by private practitioners for one month and above and treated in other TUs

The 'type of disease' at the time of re-registration was correctly classified based on initial treatment outcome for 351 of 444 (79%): 'treatment after default' 87% (128/147), 'failure' 82% (92/112) and 'relapse' 71% (131/184) of patients.

Table 4 describes the treatment outcome of 699 smear positive patients (after excluding 3 patients 'transfer out') of the total 803 Category II patients registered during the study period of which 352 were re-registered and the remaining 344 were initially registered. The successful treatment outcome was significantly lower {132 of 352 (38%) vs 168 of 344 (49%),  $P < 0.01$ } among re-registered patients. This was mainly due to the significantly higher default, particularly among patients typed as 'treatment after default' (67 of 117 vs 79 of 215,  $p < 0.01$ ). However, the failure was similar in the two groups.

## DISCUSSION

The overall treatment outcome among Category II patients reported here is similar to another study<sup>2</sup> on re-treatment outcome of smear positive patients. Hence we analysed the outcome of patients initially registered as Category II and re-registered to Category II.

The main findings of the present study were that 68% of the failures and 23% of the defaulters from Category I treatment were only re-registered. This brings forth the need to motivate patients who fail in Category I regimen to restart treatment and prompt default retrieval actions to reduce 'default'. The proportion was much less among Category II failures and defaulters. The RNTCP recommendation to refer failures of Category II to higher institutions for further management could explain the lower re-registration of failure to Category II. We were unable to estimate the proportion of patients re-registered among those relapsed since we do not have the actual number relapsed among successful treatment completion. However, the proportion of relapse cases registered was lower than the relapse rate of 12% reported from an earlier study from the same area<sup>3</sup> where patients with treatment success were followed-up. This stresses the point that patients who have successfully completed treatment need

to be advised to report if they develop chest symptoms. The high proportion of defaulters not returning for treatment is of concern for TB control since they may continue to spread the disease and calls for attempts to retrieve these patients and put them on treatment. This would also help to reduce the delay in restarting treatment for these patients.

The higher default rate among the re-registered patients under type 'default' could be because they continue to default suggesting the need for more intense and continuing motivation efforts for these patients. No significant difference in default was observed for those declared 'failure' between the two groups.

RNTCP as a policy emphasizes on the new smear positive patients and their treatment outcome. Our findings suggest that it is essential to monitor re-treatment patients with same vigour to reduce default and improve their treatment outcome.

A limitation of the study was that the defaulted patients were not visited to find out reason and no attempt was made to visit the patients who didn't turn-up for re-starting treatment. Another limitation is that the analysis is based on self-reporting patients who were re-registered in the same TU, but did not cover patients who would have reported to any other TU or to private sector.

**In conclusion, the study demonstrated that higher default occurred among re-registered patients resulting in low successful treatment outcome. The fact that only 23% of patients who had defaulted were re-registered and the higher default (57%) among patients re-registered emphasizes the need to motivate them for continuing the treatment. Studies are required to find out reasons for those who did not turn up for re-treatment and evolve methods to ensure their return to treatment.**

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### **Sixty-First National Conference on Tuberculosis and Chest Diseases**

**The Sixty-First National Conference on Tuberculosis and Chest Diseases** will be held at RNT Medical College, Udaipur (Rajasthan) from 23<sup>rd</sup> to 25<sup>th</sup> February, 2006. Registration-cum-brochure forms can be obtained from the Secretary General, Tuberculosis Association of India, 3-Red Cross Road, New Delhi-110 001.